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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/809,621	06/02/1997	NOBUTAKA IDA	599-158P	7804

2292 7590 07/19/2002

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 07/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
08/809,621

Applicant(s)
Ida et al

Examiner
Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-17 and 20-24 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 28, 29 6) ☐ Other:

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Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 18 and 19 have been canceled. Claims 14 and 21 have been amended. Claims 22-24 have been added. Claims 13-17 and 20-24 are under consideration.
3. The rejection of Claims 13, 14, 16, 17 and 20 under 35 U.S.C. 112, first paragraph, is withdrawn.
4. The rejection of claims 15 and 17 under 35 U.S.C. 103(a) as being unpatentable over Manolagus (Bone, 1995, 2 Suppl., 63S-67S) in view of Zawatzky et al (Journal of Virology, 1991, Vol. 65, pp. 4839-4846) is withdrawn.
5. The rejection of claims 13, 14, 16, 20 and 21 under 35 U.S.C. 103(a) as being unpatentable over Manolagus (Bone, 1995, 2 Suppl., 63S-67S) in view of Zawatzky et al (Journal of Virology, 1991, Vol. 65, pp. 4839-4846) is maintained for reasons of record. The rejection of newly added claims 22 and 23 is made for the same reasons of record. Applicant argues that at the instant filing date it was not clear how INF beta would affect Il-6 levels. This has been considered but not found persuasive. The instant application has a priority date of 1995. The cytokine Il-6 was formerly termed INF- beta-2 as it co-purified in cellular preparations of INF-beta. Thus older preparations of INF-beta could contain substantial amounts of Il-6 which would negate the opposing effects of INF-beta, however, the INF beta used by Zawatsky in 1991 was recombinant INF-beta, and thus it can be concluded that said INF-beta preparation was free of Il-6 activity.

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New Grounds of Rejection

6. Claims 13, 17, 20, 22, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Haase and Lange (Tumor Diagnostik & Therapie, 1988, Vol. 9, pp. 96-99. Claim 17 is drawn to treating a patient with INF beta or an INF beta inducer, wherein said patient has an osteoclast disorder related to the presence of a bone metastases from mammary carcinoma, lung cancer, prostate cancer, thyroid gland carcinoma, renal cancer, digestive tract cancer, esophageal cancer. New claim 24 is drawn to the treatment of a patient with INF-beta or and INF-beta inducer, said patient having an osteoclast bone disorder due to multiple myeloma, bone metastases from mammary carcinoma, lung cancer, thyroid gland cancer, renal cancer, colon cancer, digestive tract cancer, and esophageal cancer.

Haase and Lange disclose the treatment of osteolytic metastatic lesions to the bone, wherein the metastatic lesions were the result of mammary, lung and renal cancer.

Conclusion

7. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on May 1, 2002 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

July 1, 2002



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